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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,008	12/20/2000	Marina Chuenkova	1322.1028-001	7228

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EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/19/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,008

Applicant(s)

CHUENKOVA ET AL.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-39 and 42-58 is/are pending in the application.
- 4a) Of the above claim(s) 34-39 and 51-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-33 and 42-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 25-39 and 42-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 2-11-03 has been entered into the record and has been fully considered.

2. Claims 1-24, 40 and 41 are canceled. Claims 25-39 and 42-58 are pending

Election/Restriction

3. Applicant's election with traverse of Group III in Paper No. 9 is acknowledged.

The traversal is based upon the identification of a particular sequence element that links alternative sequences as detailed in the traversal. This traversal is found persuasive to the extent of SEQ ID NO:14 and linking claims thereto. In a telephone inquiry by the Examiner with Applicant's representative Robert Underwood it was affirmed that applicant's election is of Group III to the extent of SEQ ID NO:14. It was further clarified that SEQ ID NO:14 is equivalent to SEQ ID NO:34 residues 379-394. Applicant's assert that the elected invention reads on claims 25-39 and 42-58. However, the Examiner notes that only claim 25 and dependent claims thereto (26-33 and 42-50) are clearly drawn to elected SEQ ID NO:14 and are so linked. Claims 34-39 and 51-58 are not drawn to elected SEQ ID NO:14 and are not so linked. In particular, it is noted that claim 51 is not drawn to the SEQ ID NO:34 element but to a variant with fewer amino acid residues and which is only 90% identical with a portion of SEQ ID NO:34. Accordingly, claims 34-39 and 51-58 are not drawn to the elected invention of SEQ ID NO:14. Thus, these claims do not read on the elected invention and are therefore withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

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4. Claims 34-39 and 51-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 25-33 and 42-50 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In particular the claims are deemed to read on a product of nature. Applicants should amend the claims to reflect the hand of man, i.e., "An isolated..."

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 25, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by IDS reference AX, Pereira et al., J. Exp. Med., 174:179-91, 1991.

Pereira et al., teach trypanosoma cruzi Neuraminidase sequence corresponding with 100% identity to a peptide comprising SEQ ID NO:14. As the peptide is the same peptide it inherently provides for neurotrophic activity (claim 25). Pereira teaches bacterial lysates in PBS comprising neuraminidase and exhibiting neuraminidase activity and thus the reference teaches a composition comprising the peptide and a physiologically acceptable carrier (claim 27). Thus, the reference teachings anticipate the claimed invention.

9. Claim 25, 27, 30 and 33 are rejected under 35 U.S.C. 102(a) as being anticipated by IDS reference AZ, Chuenkova et al., Biochem. & Biophys. Res. Comm., 262:549-556, 1999 or in the alternative under 35 USC 103(a) as obvious over Chuenkova et al., Biochem. & Biophys. Res. Comm., 262:549-556, 1999.

Chuenkova et al., teach trans-sialidase of T. cruzi which comprises two activities a neuraminidase that results in sialic acid release from complex carbohydrates and a sialyl-transferase activity catalyzing the transfer of sialic acid to acceptors, see in particular columns 1-2 paragraph spanning and pp. 550 trans-sialidase and neuraminidase activity assays. Chuenkova et al., also teach various deletion and fusion mutants that exhibit various sequence variations from the wild-type form, see in particular p. 552-554. The proteins are expressed and purified followed by elution in NaCl and thus the peptides are provided in a physiologically acceptable carrier, see in particular p. 550, Expression and purification of rTS. Chuenkova et al., are silent to the amino acid sequence of the T. cruzi neuraminidase/trans-sialidase. However the

enzyme clearly exhibits the noted activities and thus is considered to be either the same protein or a 90% variant to a protein comprising the required sequence of SEQ ID NO:14. The USPTO has insufficient resources to determine whether or not the protein comprises the noted sequence or is in fact a 90% variant of the T. cruzi neuraminidase of Periera et al., for example that shares 100% identity as set forth above. Thus, the Examiner has insufficient facts to determine whether the Chuenkova proteins are "inherently the same" or obvious since the examiner cannot determine how the proteins and mutants differ. Since the record does not allow the determination of if and how the claimed methods differ, the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Specifically, that the Chuenkova proteins neither comprise SEQ ID NO:14 or sequences that are 90% variants. Note the case law of In re Best 195 USPQ 430, 433 (CCPA 1977).

Status of Claims

10. No claims are allowed.

11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
May 12, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
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